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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,295	07/06/2001	Evi Kostenis	02481.1745	7672

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	15

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/899,295	Kostenis
Examiner	**Art Unit**
John Ulm	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-170* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-170* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1) Claims 1 to 170 are pending in the instant application.

2) Claims 57 to 112 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends. The processes of claims 1 to 56 are analytical and do not produce or use the compounds of claims 57 to 112. Therefore, a compound which is encompassed by any of claims 57 to 112 would not infringe any of the analytical processes of claims 1 top 56. See M.P.E.P. 608.01(n)III..

3) Claims 113 to 170 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

> "Since the decisions in In re Weber **,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

The amino acid sequences of SEQ ID NO:2, 4, 6 and 8 do not share a common utility which is based upon a shared special technical feature lacking from the prior art.

4) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 to 56, drawn to a receptor activation assay, classified in class 436, subclass 501.

II. Claims 57 to 112, drawn to a compound of unspecified constitution, classified in classification undeterminable.

III. Claims 113 to 158, and 168, only in so far as they relate to an isolated nucleic acid encoding SEQ ID NO:2, classified in class 435, subclass 69.1.

IV. Claims 113 to 158, and 168, only in so far as they relate to an isolated nucleic acid encoding SEQ ID NO:4, classified in class 435, subclass 69.1.

V. Claims 113 to 158, and 168, only in so far as they relate to an isolated nucleic acid encoding SEQ ID NO:6, classified in class 435, subclass 69.1.

VI. Claims 113 to 158, and 168, only in so far as they relate to an isolated nucleic acid encoding SEQ ID NO:8, classified in class 435, subclass 69.1.

VII. Claims 159 to 166, only in so far as they relate to an assay which employs a host cell comprising a recombinant nucleic acid encoding SEQ ID NO:2, classified in class 435, subclass 7.21.

VIII. Claims 159 to 166, only in so far as they relate to an assay which employs a host cell comprising a recombinant nucleic acid encoding SEQ ID NO:4, classified in class 435, subclass 7.21.

IX. Claims 159 to 166, only in so far as they relate to an assay which employs a host cell comprising a recombinant nucleic acid encoding SEQ ID NO:6, classified in class 435, subclass 7.21.

X. Claims 159 to 166, only in so far as they relate to an assay which employs a host cell comprising a recombinant nucleic acid encoding SEQ ID NO:8, classified in class 435, subclass 7.21.

XI. Claim 167, only in so far as it relates to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in class 530, subclass 350.

XII. Claim 167, only in so far as it relates to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:4, classified in class 530, subclass 350.

XIII. Claim 167, only in so far as it relates to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:6, classified in class 530, subclass 350.

XIV. Claim 167, only in so far as it relates to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:8, classified in class 530, subclass 350.

XV. Claims 169 and 170, only in so far as they relate to a method of producing antibodies by employing a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in class 530, subclass 388.22.

XVI. Claims 169 and 170, only in so far as they relate to a method of producing antibodies by employing a polypeptide comprising the amino acid sequence of SEQ ID NO:4, classified in class 530, subclass 388.22.

XVII. Claims 169 and 170, only in so far as they relate to a method of producing antibodies by employing a polypeptide comprising the amino acid sequence of SEQ ID NO:6, classified in class 530, subclass 388.22.

XVIII. Claims 169 and 170, only in so far as they relate to a method of producing antibodies by employing a polypeptide comprising the amino acid sequence of SEQ ID NO:8, classified in class 530, subclass 388.22.

The inventions are distinct, each from the other because:

The host cells of inventions III to VI are each related to the assay of invention I as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the claimed assay can employ a cell which naturally expresses a G protein-coupled receptor and which, therefore, would be materially different from the host cells of inventions III to VI. Further, because the assay of invention I is not limited to the specific receptor proteins recited in inventions III to VI it can be practiced with a materially different product.

The cells of each of inventions III to VI are related to each of the assays of inventions VII to X as product and process of use. They are shown to be distinct because the cells, as claimed, can be used to propagate the recombinant nucleic acid contained therein, which is a process that is materially different from the assays of each of inventions VII to X.

The assy of invention I, the compound of invention II, the isolated polypeptides of inventions XI to XIV, the assay of inventions VII to X and the method of producing antibodies of inventions XV to XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation to achieve different effects and the claimed compounds are not produced by or employed in the claimed methods.

The compound of unspecified constitution which is invention II, the nucleic acids of inventions III to VI, the polypeptides of inventions XI to XIV and the antibodies produced by the methods of inventions XV to XVIII are ten different chemical compounds each of which can be made and used without the others. These ten different compounds lack unity of invention because they do not share a common utility which is based upon a common structural feature or combination of features lacking from the prior art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6) Claims 1 to 112 are generic to a plurality of disclosed patentably distinct species of host cell as listed, for example, in clam 14, a plurality of disclosed patentably distinct species of G protein or pair of G proteins as listed in paragraph 30 of the instant specification, a plurality of disclosed patentably distinct species of signal transduction pathway and a plurality of disclosed patentably distinct species of G protein having a specified amino acid sequence as listed in claim 114. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of host cell, G protein combination, signal transduction pathway, and G protein amino acid sequence, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800